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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GARVEY, TARA L	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,694	DONNELLY ET AL.	
	Examiner	Art Unit	
	Tara L Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4-6, 12-16 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7-11 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a response to restriction, filed 12/3/03, in which claims 1, 3, 9 and 11 were amended and claims were 4-6, 12-16 and 18-25 were cancelled. Claims 1-3, 7-11 and 17 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I directed to claims 1-11 and 17-18 and species election of V1Jns-GA-HA in response to a restriction requirement filed on 4/22/04 is acknowledged. The traversal is on the ground(s) that a species election is not necessary for the claims of Group I as currently amended since a search burden does not exist. This is not found persuasive because the plasmids have different biological and chemical properties unique to their structure. While searches may overlap, they also extend beyond one another. A reference could anticipate one plasmid backbone and not another plasmid backbone. For example, a reference could teach the use of pnRSV in the DNA construct of claim 1, but not teach the use V1Jns in this construct.

The requirement is still deemed proper and is therefore made FINAL.

The V1J and the V1Jns plasmid backbones have been rejoined.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

A break in continuity has occurred in the listed continuing data. Priority will only be given to application 08/461,268 with a date of June 5, 1995.

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the

prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7-11 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to a DNA construct that is a plasmid that encodes an influenza virus gene and is able to induce an immune response in animal cells. Claim 2 is drawn to the product of claim 1 in which the influenza virus gene is for the nucleoprotein, hemagglutinin, polymerase, matrix, or non-structural components. Claims 7, 9-11 are drawn to a method of immunization for human influenza virus using the DNA construct of claim 1 or claim 2 and administering the DNA in an acceptable solution into tissues in vivo. Claim 3 is drawn to a plasmid DNA construct that expresses an influenza virus gene upon introduction into vertebrate tissue in vivo and induces an immune response. Claim 8 is drawn to the product of claim in which the vertebrate is immunized with DNA construct in an effective amount.

Claims 1-3, 7-11 and 17 are drawn to or encompass a plasmid, V1Jns. The specification fails to provide an enabling disclosure in regard to the generation of the V1Jns vector which contains neo resistance gene and an Sfi1 site for integration (described in example 12 on page 66). The V1Jns vector was derived from the V1J vector (example 6, pages 51-52). The V1J vector has an unusual properties in that it "gave much higher yields of DNA" (page 52, lines 15-16) and higher expression of heterologous genes compared to the V1 vector from which it was partially derived (page 52, lines 18-19). Although the sequence listing for V1J is disclosed (SEQ. ID 10), the

specification indicates that the "structure was verified by sequence analysis of the junction regions" (page 52, lines 16-19) and therefore, the sequence must have been compiled from other sequences and not confirmed in its entirety. Since V1Jns is required for the practice of the claimed invention, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. Since it does not appear to be obtainable, this enablement requirement may be satisfied by a suitable deposit.

The application discloses the V1Jns plasmid that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or

statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

In regard to the ability to use the V1Jns plasmid backbone in a DNA vaccine, enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art, relative skill in the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claim, with the most relevant discussed below.

Nature of the invention: The rejected claims are drawn to a DNA construct containing the V1Jns plasmid backbone and an influenza gene. The V1Jns construct has the added feature of being able to integrate into the host genome. The DNA construct will be delivered by in an effective amount to a vertebrate to generate an immune response against influenza virus. The DNA can be delivered as naked DNA,

with a liposome, with an adjuvant or with a transfection facilitating agent by various injection routes.

Guidance in the specification/Existence of a working example: The specification describes how to use vectors composed of the V1J backbone, but not the V1Jns backbone. Working examples describe how to immunize vertebrates with constructs expressing NP and HA from the V1J backbone and measure the immune response via survival from challenge with influenza virus, antibody response and cytotoxic T lymphocyte response. The specification does not describe any experimental data produced using the V1Jns DNA constructs expressing influenza genes to generate an immune response in vertebrates against influenza virus. Therefore, there is no evidence provided that other vectors including V1Jns can elicit a protective immune response by the above methods that would be comparable to the V1J vectors. In addition, the unique feature added to the V1J vector was the Sfi1 linker which gave it the ability to integrate into the host genome. The specification has not provided any evidence that integration actually occurs.

State of the art: At the time of the applicants' invention, the use of plasmid DNA vectors as a method of vaccination against viral infection was known (Robinson et al. US 5,643,578). In addition, it had been determined that the direct administration of these DNA vaccines into animal cells in vivo could induce both a humoral and cell mediated immune responses (Fulgner et al US 5,589,466).

Predictability of the art: With the addition of the Sfi1 linker site, the V1Jns should have the ability to integrate into the host chromosome. The applicants' own publication

states that a characteristic of a good plasmid for a DNA vaccine is one that does not have the capability to integrate into the host genome (Montgomery et al DNA and Cell Biology, Vol. 12, Issue 9, pages 777-783, 1993). A major problem with integration into the host genome is the inability to predict the location of the insertion site. Due to this unpredictability, insertional mutagenesis can occur. One is unable to predict the effect this mutagenesis will have on the host and on the expression of the heterologous gene. Insertional mutagenesis has been documented with the use of retroviral vectors expressing heterologous genes and resulted in an increased rate of cancer. Manickan et al state that no evidence exists that integration into genomic DNA occurs, but if integration did occur insertional mutagenesis is possible (Manickan et al Critical Review Immunology, 1997, volume 17(2), pages 139-54; see page 141).

Quantity of experimentation: Since the use of the V1Jns plasmid in a vaccine has not been demonstrated, constructs expressing influenza genes from this plasmid would have to be tested in an animal model. The ability of the V1Jns DNA vaccines to generate an effective immune response would need to be determined by protection studies involving challenge with influenza virus and measurement of antibody and CTL responses. All these experiments would initially have to be performed with various amounts of DNA to determine the effective dose. The best route of administration and method of introduction of the DNA would also need to be analyzed. In addition, experiments would need to be conducted to determine if the V1Jns construct is able to integrate into the host genome and how this would affect its ability to induce an immune

response. To determine the effectiveness of the V1Jns construct, the experimentation would be extensive.

In view of the unpredictable nature of the art, the lack of direction in the specification, the lack of a working example and the amount of experimentation to determine the efficacy of the V1Jns plasmid backbone for use in a DNA vaccine, the experimentation would have been undue. Thus, it would require undue and unpredictable experimentation for one of skill in the art to make and use the claimed invention. Therefore, the claimed invention of a DNA construct with a V1J or V1Jns plasmid backbone driving the expression of an influenza gene for use as a vaccine is not considered to be fully enabled by the instant specification.

Claims 1, 7, 10 and 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claim 11 is drawn to a method of administering DNA to a vertebrate as naked DNA or as a mixture with a liposome, and adjuvant or a transfection facilitating agent.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art, relative skill in the art and the amount of experimentation necessary. All of the Wands

factors have been considered with regard to the instant claim, with the most relevant discussed below.

The specification states that the DNA vector "may be associated with an adjuvant known in the art to boost immune responses, such as a protein or other carrier" (page 32). However, the proposed use of the adjuvants is not clear. Adjuvants are normally used to boost the humoral immune response, but the DNA vaccine proposed in this invention is required to enter the cell and express the heterologous gene to produce proteins recognized by the immune system. It is unclear what role the adjuvant would have played. The specification does not describe how to use the DNA vaccine in combination with an adjuvant or suggest potential useful adjuvants. Working examples describe different routes to adminster the DNA to the cells, but working examples do not exist that describe an effective dose of the adjuvant, manner in which to administer the adjuvants, or the effect of the adjuvants on the desired immune response to the influenza virus.

Due to the lack of guidance in the specification, the lack of working examples, and the unpredictability of the effect of the adjuvant, it would have required undue experimentation to determine the dose of an acceptable adjuvant to obtain the desired immune response in combination with the DNA vaccine for one skilled in the art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3,7-9,11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of "specific immune response" is unclear. What would be considered a "specific immune response"?

Claim 3 is vague and indefinite because the phrase "induces neutralizing antibody against human influenza virus, influenza virus specific cytotoxic lymphocytes, or protective immune responses" is unclear. The phrase reads as if the neutralizing antibodies are against the "cytotoxic lymphocytes" and the "protective immune response", but the antibodies are not intended to be directed against these immune responses. In addition, the "said DNA pharmaceutical" in lines 3-4 lacks antecedent basis.

Claims 7-9 is vague and indefinite because it is unclear what is considered to be protection from infection of human influenza virus. Is the protection referring to the initial infection or a later process during the infection. In addition, it is not clear whether the protection is directed to the cells or the organism. The phrase "prophylactically effective amount of DNA" is unclear because the amount of DNA necessary to be effective is not defined.

Claim 11 is vague and indefinite because what constitutes a "carrier" is not defined and therefore what should not be in the solutions is not defined. The phrase "mixture of DNA and liposome" is unclear because the ratio of the components in the

mixture is not known. In addition it is unclear what encompassed within the phrase "adjuvant or a transfection facilitating agent".

Claim 17 is vague and indefinite because "the organism" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al (DNA and Cell Biology, Vol. 12, Issue 9, pages 777-783, 1993). Claims 1-3 and 7-11 have been described above.

Montgomery et al teach the construction of DNA vectors composed of the V1J plasmid backbone expressing the nucleoprotein or hemagglutinin influenza gene (pages 778-779), immunization of mice with the DNA constructs by the intramuscular route (page 778) and measuring the immune response generated by the immunization with the DNA vectors by survival after challenge with influenza virus and neutralizing antibody response and cytotoxic T lymphocyte response (pages 780-782). Thus, Montgomery et al teaches all that is recited in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3,7,8,10,11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al (DNA and Cell Biology, Vol. 12, Issue 9, pages 777-783, 1993) in view of Felgner et al (US 5,580,859). Claims 1,3,7,8,10,11 and 17 have been described above.

Montgomery et al do not teach the administration of the DNA construct with a delivery system such as a liposome or a transfection facilitating agent. In addition, they do not teach the administration to humans.

Fulgner et al teach immunizing vertebrates with naked DNA construct by direct injection into skin or muscle (columns 7, 8, column 9 lines 32-50, 64-67 and column 10 lines 1-8 and 20. They also teach methods of administering the DNA construct such as using liposomes (columns 9, 20, 25 and 26) or transfection reagents (column 33). They teach the advantage of introducing the DNA into the cell directly is so that the antigen will be recognized in the context of a class I MHC molecule and generate a cytotoxic T lymphocyte (CTL) response (column 8, lines 41-55, column 20, lines 54-67, column 21, lines 1-6 and column 19, example 19). They teach that such a system can be used in mammals such as humans (see claims). It would have been obvious to one of ordinary skill in the art to try multiple methods to introduce DNA into a cell such as using naked DNA, DNA with a liposome or DNA with a transfection facilitating reagent. One would have been motivated to do so in order to receive the expected benefit of determining the best method to introduce the DNA expressing the antigen into the desired cells to obtain a CTL response in addition to a neutralizing antibody response to the antigen. The enhanced immune response would likely provide better protection from various strains of virus. Absent of any evidence to the contrary, there would have been a reasonable expectation of success in injecting the naked polynucleotide directly to the cells DNA construct to cells since the type of constructs were of a similar nature.

Claims 1-3, 7-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al (DNA and Cell Biology, Vol. 12, Issue 9, pages

777-783, 1993) in view of Robinson et al (US 5,643,578). Claims 1-3, 7-11 and 17 have been described above.

Montgomery et al does not teach administration of the DNA construct to animal tissues other than muscle.

Robinson et al teaches a DNA plasmid construct expressing hemagglutinin from influenza virus (column 2, lines 25-30 and column 3, lines 56 to 67), the administration of the DNA construct in a solution with adjuvants or substance for the uptake of the DNA (column 3 lines 1-6), and introduction of an effective amount of the DNA construct into vertebrate tissue by various inoculation routes to produce an immune response (abstract, columns 7 and 8, table 5 and claims). It would have been obvious to one of ordinary skill in the art to try various inoculation routes such as intranasal, intraperitoneal, intravenous, intradermal, intramuscular or subcutaneous. One would have been motivated to do so in order to receive the expected benefit of determining the best route of administration to obtain the most effective immune response. Absent of any evidence to the contrary, there would have been a reasonable expectation of success in introducing the DNA construct to different tissues through various inoculation routes since the constructs were of similar nature and were designed to express in mammalian cells.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history

information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG

JAMES KETTER
PRIMARY EXAMINER

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.